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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,009	05/03/2005	Ruth Chiquet-Ehrismann	1-32411A/FMI	1199

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
GUSSOW, ANNE	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
04/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,009	CHIQUET-EHRISMANN ET AL.	
	Examiner	Art Unit	
	ANNE M. GUSSOW	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,14-52,58-60 and 65-68* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 14-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-60 and 65-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-10 and 14-52 remain withdrawn.

Claims 60 and 68 have been amended.

Claims 11-13, 53-57, 61-64, and 69-72 have been cancelled.

2. Claims 58-60 and 65-68 are under examination.

3. The finality of the previous office action is withdrawn. The following office action contains NEW GROUNDS of Rejection.

Objections Withdrawn

4. The objection to claim 11 is withdrawn in view of applicant's cancellation of the claim.

Rejections Withdrawn

5. The rejection of claims 53-57, 60-64, and 68-72 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's cancellation of claims 53-57, 61-64, and 69-72 and amendment to claims 60 and 68.

6. The rejection of claims 11-13 and 53-57 under 35 U.S.C. 102(e) as being unpatentable over Ni, et al. is withdrawn in view of applicant's cancellation of the claims.

NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 58-60 and 65-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni, et al. (US 2002/0151009, filed August 28, 2001, as cited in a previous office action).

The claims recite an isolated antibody that specifically recognizes amino acids 791-1054 of the polypeptide having the amino acid sequence shown SEQ ID NO: 4, for the manufacture of a medicament, wherein said medicament is for the prophylaxis or treatment of breast cancer. An isolated antibody that specifically recognizes one or more of the three C-terminal fibronectin III repeats of tenascin W, wherein said antibody specifically recognizes one or more of the three C-terminal fibronectin III repeats in the region defined by amino acids 791-1054 of the tenascin W polypeptide having the amino acid sequence shown SEQ ID NO: 4, for the manufacture of a medicament, wherein said medicament is for the treatment of breast cancer.

Ni, et al. teach antibodies that bind to a human protein homolgous to the tenascin W protein (page 15 paragraphs 178-180 and table 1, clone 13 SEQ ID No. 29). Ni, et al. teach that antibodies of the invention may be polyclonal or monoclonal (page 32, paragraph 320). Ni, et al. teach antibodies in therapeutic compositions (page 41, paragraph 387) for the treatment of hyperproliferative diseases including breast cancer (page 67, paragraph 671).

As set forth in a previous office action, the C terminal region of the protein of Ni, et al. shares 84% homology with the instant SEQ ID No. 4. Since Ni, et al. teach polyclonal antibodies and polyclonal antibodies bind to multiple epitopes of a single protein, the polyclonal antibody of Ni, et al. would bind to the C terminal region of SEQ ID No. 4 and all the limitations of the claims have been met.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 58, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber, et al. (Journal of Neurobiology, 1998. Vol. 35, pages 1-16) in view of Campbell (Monoclonal Antibody Technology, 1984. pages 1-32).

The claims have been described supra.

Weber, et al. teach the sequence of zebrafish tenascin-W protein. Weber, et al. teach the C-terminal fibronectin III domains are not closely related to any particular fibronectin domain in other proteins of the tenascin family. Weber, et al. do not teach an antibody that binds to tenascin W. This deficiency is made up for in the teachings of Campbell.

Campbell teaches that it is routine to produce monoclonal antibodies to macromolecules (page 29).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the protein of Weber, et al. to produce an antibody as taught by Campbell.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced an antibody that recognizes the C terminal fibronectin III region of tenascin W because Weber, et al. teach that the C terminal fibronectin III repeats are different from other members of the tenascin family, thus an antibody to this region would differentiate tenascin W from other members of the tenascin family of proteins. Additionally, Campbell teaches that it is customary to clone the genes coding for a macromolecule and make monoclonal antibodies to it. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the tenascin W protein of Weber, et al. and produce an antibody as taught by Campbell.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the references.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is

(571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

April 2, 2008

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643